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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,382

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Glenn D. Prestwich

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05/21/2008

GARDNER GROFF GREENWALD & VILLANUEVA. PC
2018 POWERS FERRY ROAD
SUITE 800
ATLANTA, GA 30339

EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

05/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,382	Applicant(s) PRESTWICH ET AL.	
	Examiner SUN JAE Y. LOEWE	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-10-2006;3-28-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-9,11,13-15,17-25,32-36,38-40,42-44,46-48,50,51,53-55,57-59,61,62,64-68,71,73-75,77-88

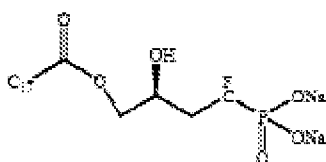
Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6-7,11,13-15,17-25,32-36,38-40,42-44,46-48,50,51,53-55,57-59,61,62,64, 65, 67,68,71,73-75,77-88

DETAILED ACTION

1. Claims 1-4, 6-9, 11, 13-15, 17-25, 32-36, 38-40, 42-44, 46-48, 50, 51, 53-55, 57-59, 61, 62, 64-68, 71, 73-75, 77-88 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I, and species below, in the reply filed on March 28, 2008 is acknowledged.



The traversal is on the ground(s):

- technical features. However, the products of Group I and the methods Group II, III, and IV are
- a) linked by common structural features recited within claim 1, formula I.
- Applicant asserts that it would not be a serious burden on the Examiner to search the
- compositions recited in claims 1-4, 6-9, 11, 13-15, 17-25, 32-36, 38-40, 42-44, 46-48, 50, 51, 53-
- b) 55, 57-59, 61, 62, and 64-67 and the methods recited in claims 68, 71, 73-75, 77-85, and 86-88.

The arguments have been considered, however, they are not persuasive for the following reasons:

- a) The technical feature linking the inventions claimed in Groups I-IV is not a special technical feature for the reasons provided in the restriction requirement.
- b) The criteria of burden is not applicable for determining propriety of restriction for applications filed under 35 USC 371.

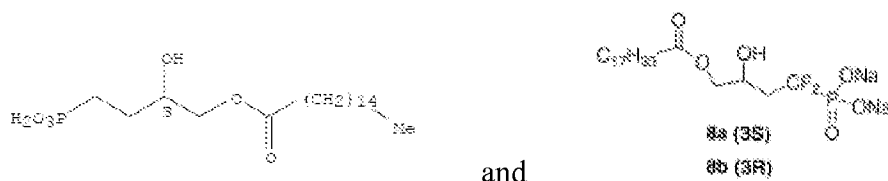
The restriction requirement is still deemed to be proper and is hereby made FINAL.

3. MPEP § 803.02 provides the following guideline:

“Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable **, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration.”

The elected compound was not allowable (see Section 11). Furthermore, the non-elected species



are anticipated by the prior art (see Sections 9 and 10). Thus, the provisional election was given effect. Currently, all non-elected species are withdrawn from further consideration.

4. Claims 3, 7, 9, 11, 13-15, 17-25, 32-36, 38-40, 42-44, 46-48, 50, 51, 53-55, 57-59, 61, 62, 64, 65, 67, 68, 71, 73-75 and 77-88 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Applicant timely traversed the restriction requirement in the reply filed on March 28, 2008.

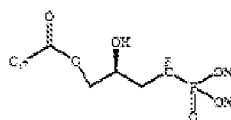
Information Disclosure Statement

5. The information disclosure statements (dated March 10, 2006 and March 28, 2008) were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The statements were

considered. Signed copies of form 1449 are submitted herewith. The crossed out references were not considered because copies were not provided.

Claim Objections

6. Claims 1, 2, 8 and 66 objected to for containing non-elected subject matter. Currently,

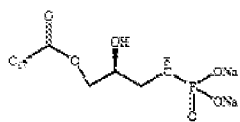


subject matter that does not include the elected species () is considered to be non-elected subject matter.

7. Claim 1 objected to because of the following informality. The claim refers to “or the pharmaceutically acceptable salt...” The term “the” implies a single entity, so it is unclear what compound “the pharmaceutically acceptable salt” refers to. It is suggested for Applicant to replace the term “the” with the term “a” if the intention is to claim, in the alternative, all pharmaceutically acceptable salts of the compounds of Formula I.

Specification

8. The specification is objected for the following reason. Multiple compounds depicted in Tables 1 and 2 do not have complete molecular formulas. For example, the elected species of



appears to be missing the number of hydrogen atoms attached to the C17

moiety. Appropriate clarification and correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2 and 66 rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al. The reference teaches the compound shown in Section 3.

U=W=oxygen;

R1=Na;

Z=CF₂;

Y1=H; Y2=OH;

V=absent;

X1=-OC(O)-R3 where R3 is alkyl; X2=H.

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10. Claims 1, 2 and 66 rejected under 35 U.S.C. 102(b) as being anticipated by Jalink et al.

The reference teaches the compound shown in Section 3.

U=W=oxygen;

R1=H;

Z=CH₂;

Y1=H; Y2=OH;

V=absent;

X1=-OC(O)-R₃ where R₃ is alkyl; X₂=H.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

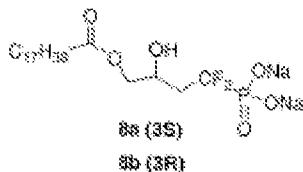
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1, 2, 8 and 66 rejected under 35 U.S.C. 103(a) as being obvious over Xu et al. in view of Patani et al., further in view of Halazy et al.

Determination of the scope and contents of prior art.

The reference teaches the following compound for the same utility as instantly disclosed

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Ascertaining the differences between prior art and instant claims.

The difference between the prior art compound and the instant election is H vs. F.

Patani et al. teaches the substitution of hydrogen by fluorine as a commonly employed monovalent isosteric replacement in rational drug design (pg. 3149).

Halazy et al. further teaches fluoro-alkanephosphonates and difluoroalkanephosphonates to be adequate functional equivalents (pg. 316).

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

One of ordinary skill would be motivated, from the disclosure in the prior art, to make the modification required to arrive at the instant invention with reasonable expectation of success for obtaining a compound with the same activity. The motivation to make the change would be to make additional compounds for the quoted purpose.

Thus, the instant claims are *prima facie* obvious over the teaching of the prior art.

Conclusion

12. No claims allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074.

The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./
5-19-2008

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626